

# A Comparative Analysis of the Baska Mask versus I-Gel for General Anesthesia in Surgical Patients Undergoing Laparoscopic Cholecystectomy

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## Abstract

**Background and Aims:** Baska mask is a newly introduced membranous cuffed supraglottic device whereas I-gel is made up of thermoplastic elastomer, both suitably designed from the anatomical perspective of the airway. **Settings and Design:** We conducted randomized controlled comparative trial of the Baska mask versus I-gel in a patient undergoing laparoscopic cholecystectomy. **Subjects and Methods:** A total of 100 adult patients in the age group of 20–70 years undergoing elective laparoscopic cholecystectomy were randomly divided into two groups as follows: (1) Baska mask group and (2) I-gel group. The primary outcome was to compare oropharyngeal leak pressure (OLP) of Baska mask and I-gel groups. The secondary outcome was the ease of insertion and removal, number of attempts, insertion time, leak fraction, and laryngopharyngeal morbidity. **Statistical Analysis Used:** Demographic details were compared using the Chi-square and *t*-tests. Student's *t*-test for independent variables was used to compare means of data obtained. **Results:** Mean OLP was significantly higher in Baska mask group than I-gel group at insertion ( $29.54 \pm 1.41$  cm H<sub>2</sub>O vs.  $23.16 \pm 3.07$  cm H<sub>2</sub>O,  $P = 0.02$ ) and 30 min after insertion ( $33.54 \pm 1.16$  cm H<sub>2</sub>O vs.  $25.97 \pm 2.25$  cm H<sub>2</sub>O,  $P = 0.001$ ). Insertion time was  $12.33 \pm 2.61$  s with Baska mask and  $11.31 \pm 1.84$  s with I-gel ( $P = 0.02$ ). Insertion was very easy in 58% of patients in Baska mask and 76% of patients in I-gel ( $P = 0.03$ ). The leak fraction of Baska mask was significantly less than I-gel ( $3.56 \pm 3.6$  vs.  $7.16 \pm 2.45$ ,  $P = 0.01$ ). Laryngopharyngeal morbidity was comparable in the two groups. **Conclusion:** Baska mask is more effective in providing greater OLP compared to I-gel without any increase in laryngopharyngeal morbidity.

**Keywords:** Baska mask, cholecystectomy, I-gel, intermittent positive-pressure ventilation, masks, oropharyngeal leak pressure

## INTRODUCTION

The laryngeal mask airway (LMA) may be used to provide a routine airway for use during general anesthesia or less frequently as a conduit for tracheal intubation.<sup>[1]</sup> The supraglottic airway (SGA) device also plays a special role in the difficult airway algorithm in cases of the anticipated and unanticipated difficult airway.<sup>[2]</sup>

New improved designs of LMA have a cuff that provides a higher sealing pressure than the classic LMA and allows venting off the stomach contents through a gastric drain tube.<sup>[3]</sup> These improved devices could be used safely during anesthesia for procedures associated with a high peak pressure of airway-like laparoscopic cholecystectomy.<sup>[4]</sup>

The Baska mask (Logikal Health Products PTY Ltd., Morisset, NSW, Australia) is a new SGA device, having a noninflatable cuff with the better sealing pressure that increases with

intermittent positive pressure ventilation (IPPV) without gastric inflation and novel gastric drainage system that reduces the risk of gastric aspiration.

I-gel (Intersurgical, Wokingham, Berkshire, UK) is a noninflatable anatomically designed SGA device, composed of thermoplastic elastomer offering high seal pressure and less trauma. An integrated gastric channel offers additional protection against aspiration.

Till date, there have been few randomized studies to compare oropharyngeal leak pressure (OLP) of Baska mask with I-gel

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LMA. We hypothesized that the Baska mask would withstand higher inflation pressure with the cuffless membranous bowl without having a problem with diffusion of nitrous oxide, have a faster placement time with less laryngopharyngeal morbidity in postoperative period as compared to I-gel LMA in patients undergoing elective surgical procedures of 2 h or less duration.

## SUBJECTS AND METHODS

A randomized controlled open-label study was planned after the approval of the Institutional Ethics Committee and CTRI registration (CTRI/2017/05/008671). After obtaining informed consent, we included 100 patients in the age group of 20–70 years of either sex, who belonged to the American Society of Anesthesiologists (ASA) physical status 1 and II, scheduled to undergo elective laparoscopic cholecystectomy.

The patients with difficult airway, increased risk of aspiration, mouth opening of <2.5 cm, surgery time of more than 2 h, any pathology of the neck and upper respiratory tract, and obesity (body mass index, [BMI] >30 kg/m<sup>2</sup>) were excluded from this study.

The patients were randomly allotted to one of the two groups using a computer-generated the random table. This number was sealed in a white opaque envelope, and it was opened by a person not participating in the study after the patient was transferred to the operating table.

The preanesthetic visit of the patient was done by an anesthetist not participating in this study. The patient was evaluated for the common predictive indicators of difficult intubation such as Mallampati grade, thyromental distance, BMI, interincisor distance, their dentition, and neck movement.

On arrival in the theater, a standard anesthesia sequence was followed. After attaching standard monitoring devices to the patient, induction of anesthesia was achieved using intravenous injection of fentanyl 2 µg/kg and propofol 1.5–2 mg/kg and atracurium 0.5 mg/kg. Anesthesia was considered acceptable for device insertion when the patient did not respond to the verbal command with complete neuromuscular relaxation. The Baska mask and I-gel were thoroughly checked for their function and integrity after removal from their respective sterile pack. The manufacturer's recommendation for size selection based on patient's weight was followed. Supraglottic device insertion was done by the senior anesthesiologist who had used both the devices in 25 pilot cases before this study.

The sizes selection of Baska mask and I-gel was done according to the weight of the patients. Sizes 3 and 4 were selected for the patient with weight 30–50 kg and 50–70 kg, respectively.

In case of securing the airway with Baska mask, the patient was placed in the “sniffing” position. The Baska mask was lubricated and introduced into the mouth toward the hard palate and advanced downward until resistance was felt. When felt necessary, the tab, which is a unique feature of this device, was manipulated to negotiate the palatopharyngeal curve.

The lubricated I-gel was grasped firmly in the dominant hand, and the outlet of the cuff was directed toward the chin of the patient. The patient was placed in the “sniffing” morning air position with flexion at lower cervical joint and extension at atlanto-occipital joint. The tip of the I-gel was introduced into the mouth of the patient against the hard palate, avoiding the tongue, and glided downward and backward until a definitive resistance was felt.

The patency of the airway and the ability to ventilate were assessed by gently squeezing the reservoir bag and observing the bilateral chest movement and amplitude of waveform of end-tidal carbon dioxide. Anesthesia was maintained using isoflurane 1%–2.5% in 40% oxygen in nitrous oxide. A clear airway was defined as end-tidal carbon dioxide (ETCO<sub>2</sub>) of <50 mmHg, tidal volumes >6 ml/kg, and SPO<sub>2</sub> more than 95%. At the end of surgery, residual neuromuscular blockade was antagonized by intravenous injection neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg. Injection ondansetron 4 mg was given as prophylactic measure for postoperative nausea and vomiting. Injection diclofenac 75 mg and injection paracetamol 15 mg/kg were given intravenously for postoperative pain. The Baska mask or I-gel LMA was removed after achieving response to verbal commands, adequate spontaneous breathing, and adequate neuromuscular reversal. The device insertion was considered to be failure if there was no successful placement after three attempts. OLP test was performed after the loss of spontaneous respiration. The OLP was defined as the plateau airway pressure reached with the fresh gas flow at the rate of 6 l/min and pressure adjustment valve set to 70 cm H<sub>2</sub>O. The insertion time was noted for both the devices and was defined as the time between picking up the lubricated device and getting the first trace of the capnograph. Device stability and function were assessed by calculating the leak fraction which was defined as tidal volume inspires-tidal volume expired/tidal volume inspired (V<sub>insp</sub>-V<sub>exp</sub>/V<sub>insp</sub>) × 100. Ease of insertion, number of attempts, and ease of removal of the device were also noted. The postoperative morbidity was evaluated in the form of any trauma to the teeth, lips, and tongue, any coughing, ease to put gastric tube, the adequate clearance of the sump, and blood staining on the device. Laryngopharyngeal morbidity in the form of sore throat, dysphagia, dysphonia was evaluated at extubation and after 2 h of extubation.

Any complication in the intraoperative period and manipulation to correct the use of the supraglottic device was also documented. The device was thoroughly checked for its integrity and shape at the time of its removal.

The data were gathered for variables under study and analyzed with the help of SPSS (Windows ver. 16.0, SPSS Inc., Chicago, IL, USA) to see for the significant statistical difference and association among variables. Since there was no previous study comparing Baska mask with I-gel LMA, so we took the mean sealing pressures of the Baska mask and I-gel LMA and assuming that the increase in sealing pressure of more than

20% can be achieved with Baska mask as compared to I-gel, with Type 1 error  $\alpha$  of 0.05 and a power of 80%, and the sample size of 100 was calculated. *t*-test or Rank-sum test was used to analyze the data for continuous variables such as leak pressure and insertion attempts duration. Data analysis was done on an intention-to-treat basis. Chi-squared test or Rank-sum test as appropriate was used to analyze the categorical data. The data were considered statistically significant for all analyzed data at  $P < 0.05$ .

## RESULTS

A total of 110 patients were assessed of which 100 patients were recruited for the study as they met the inclusion criteria [Table 1]. There was a failure to achieve adequate ventilation in three patients in Baska mask group and two patients in the I-gel group, so more patients were recruited to bring the total to 100. An overall insertion rate of 94.45% was observed in the Baska mask group and 96.2% in I-gel group. The data were compared with regard to age, sex, weight, and ASA physical status [Table 2]. The surgery time was comparable in both the groups. Insertion of the device was significantly very easy in 58% of patients in Baska mask group as compared to 76% patients in I-gel group. The ease of removal of the device was also significantly very easy in 28% in

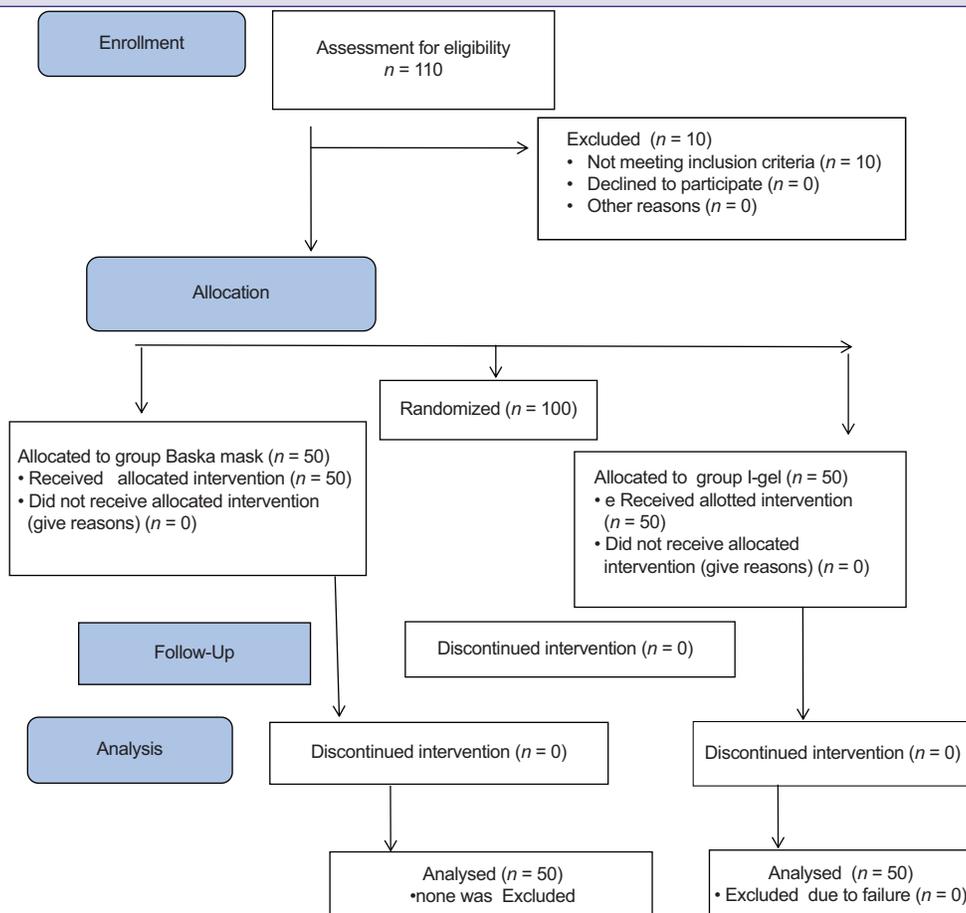
Baska mask group as compared to 56% of patients in the I-gel group. The leak fraction of the Baska mask was significantly less than the I-gel ( $3.56 \pm 3.6$  vs.  $7.16 \pm 2.45$  with ( $P = 0.01$ ); however, the leak fraction was within the admissible range of 5%–20% in both the devices [Table 3]. The ease to put the gastric tube was comparable in both the devices. Baska mask has a wider sump that allowed the insertion of larger ryles tube of size 14 Fr in size 3 and 16 Fr in Baska mask of size 4, whereas I-gel allowed the insertion of smaller sized ryles tube of size 12 Fr in both I-gel of sizes 3 and 4.

The mean OLP was significantly higher in Baska mask group as compared to I-gel group at insertion ( $29.54 \pm 1.41$  cm H<sub>2</sub>O vs.  $23.16 \pm 3.07$  cm H<sub>2</sub>O,  $P = 0.02$ ) and 30 min after insertion ( $33.54 \pm 1.16$  cm H<sub>2</sub>O vs.  $25.97 \pm 2.25$  cm H<sub>2</sub>O,  $P = 0.001$ ) [Table 3 and Figure 1]. Device insertion time was  $12.33 \pm 2.61$  s with Baska mask as compared to  $11.31 \pm 1.84$  s with I-gel ( $P = 0.02$ ) [Table 3].

There was blood on the device at removal in one case with Baska mask group as compared to none in I-gel group. The sump was bile stained in one case in each group.

There was a history of the mild sore throat in four cases in Baska mask group and three cases in I-gel group immediately after removal of the device. There was mild sore throat in one

**Table 1: Consort flow chart**

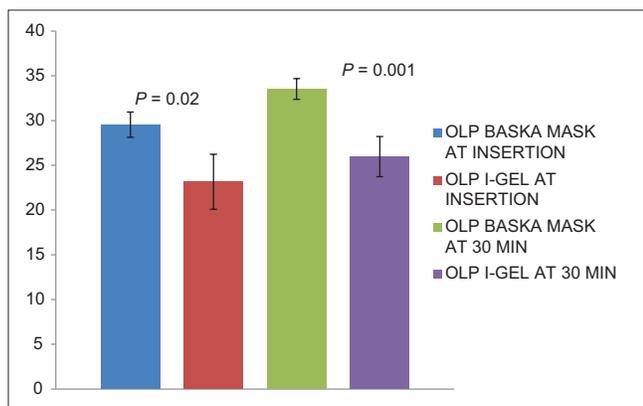


case in each group after 2 h of surgery, which got resolved within the next 4 h. None of the patients complained of dysphagia and dysphonia in both the groups [Table 4].

## DISCUSSION

An ideal SGA should be easy to insert and has less insertion time, good airway seal pressure, and minimum laryngopharyngeal morbidity.

Baska mask provides a significantly higher OLP as compared to I-gel at insertion, thereby providing greater airway protection during laparoscopic surgery. OLP with Baska mask was 29.9 cm H<sub>2</sub>O at insertion and 33.54 ± 1.16 cm H<sub>2</sub>O at 30 min of insertion as compared to 23.16 ± 3.07 cm H<sub>2</sub>O and 25.97 ± 2.25 cm H<sub>2</sub>O with I-gel. These findings were



**Figure 1:** Comparison of oropharyngeal leak pressure (cm H<sub>2</sub>O) of Baska mask and I-gel

Variable	Baska mask (n=50)	I-gel LMA (n=50)
Age (years)	41.82±12.38	41.03±10.80
Sex (male:female)	08:42	04:46
Weight (kg)	56.115±6.79	56.922±10.13
ASA 1/11	42/8	48/2
Duration of surgery (min)	52.008±10.42	68.58±12.81

LMA: Laryngeal mask airway

Variable	Baska	I-gel	P
Successful insertion (n=50) 1:2:3 (number of attempts)	43:07:00	47:03:00	0.1
Ease of insertion (n=50) 1:2:3:4 (very easy:easy:difficult:very difficult)	29:21:0:0 (58%:42%)	38:12:0:0 (76%:24%)	0.03
Insertion time, (s)	12.33±2.61	11.31±1.84	0.02
OLP; cm H <sub>2</sub> O	29.54±1.41	23.16±3.07	0.02
At insertion	33.54±1.16	25.97±2.25	0.001
30 min			
Oropharyngeal leak fraction (%)	3.56±3.6	7.16±2.45	0.01
Ease of removal (very easy:easy:difficult:very difficult)	14:36:0:0 (28%:72%)	28:22:0:0 (56%:44%)	0.002
Coughing during extubation (n=50) Yes: No	0	0	-
Blood staining on device Present: Absent	01:49:00	0	-
Sump clearance Adequate: Inadequate	49:01:00	49:01:00	0.9

OLP: Oropharyngeal leak pressure

consistent with findings observed by other authors.<sup>[5-7]</sup> The better maintenance of OLP with Baska mask is due to the cuff of the Baska mask, a recoilable membrane that inflates and deflates with the respiratory cycle, so the pressure on the surrounding tissues is never more than the peak airway pressure. This decreases the pharyngolaryngeal morbidity and also increases the oropharyngeal seal with IPPV.

Increase of OLP of the Baska mask after 30 min after the insertion provides greater sealing pressure during the pneumoperitoneum. Time for insertion of the device was significantly lesser in I-gel with the greater ease of insertion. I-gel is less bulky as compared to Baska mask making it a more handy device to insert and remove which may be responsible for lesser insertion time and easier insertion and removal. Similar mean time of insertion of 11.28 ± 2.9 s was reported by authors<sup>[8]</sup> with I-gel, whereas an insertion time of 16.6 ± 6 s and 16.43 s was reported with Baska mask in another study.<sup>[5,9]</sup> We observed the first attempt insertion success rate of Baska mask (58%) lesser than I-gel (76%), but the overall successful insertion was comparable. Baska mask has wider sumps which allow the passage of larger orogastric tube insertion. It provides rapid and adequate sump clearance. Although I-gel is more easy to insert with lesser insertion time, Baska mask provides an advantage of greater OLP which increases with positive pressure ventilation. Simultaneously, it provides larger sump clearance with dual drainage system (one with elbow connector for suction) for pharyngeal contents along with a sump reservoir and a bigger fish mouth distal gastric opening, although there was no difference in the incidence of inadequate sump clearance in both the group.

We observed significantly lower leak fraction of 3.56 ± 3.6 in Baska mask cases as compared to 7.16 ± 2.45 s in I-gel. These results were consistent with the observations by other authors<sup>[5,6]</sup> at (5%–20%) to (5%–10%) for Baska and (6%–20%) for I-gel.<sup>[10]</sup> This lesser leak may contribute to a better seal with less operative room pollution.

Postoperative laryngopharyngeal morbidity in the form of postoperative sore throat, hoarseness, and cough was comparable in the two groups. Pressure on the surrounding tissues is never more than the peak airway pressure in case

**Table 4: Laryngopharyngeal morbidity**

Complications	Baska	I-gel	P
Sore throat (none, mild, moderate, or severe) After extubation	46:04:00	47:03:00	0.9
At 2 h	49:01:00	49:01:00	0.9
Dysphagia (none, mild, moderate, or severe) After extubation	0	0	0.99
dysphagia at 2 h	0	0	-
Dysphonia (none, mild, moderate, or severe) After extubation	0	0	0.99
Dysphonia at 2 h	0	0	-

of Baska mask due to membranous cuff, thus decreasing the laryngopharyngeal morbidity as observed in other study.<sup>[6]</sup> I-gel is the cuffless device of soft consistency with reduced trauma to perilaryngeal tissue leading to less laryngopharyngeal morbidity as reported by other authors.<sup>[11]</sup>

Limitation of the study is that the findings may not be applicable to patients with difficult airway and nonparalyzed patients. Second, we did not observe OLP in the different position of the patient. It was an open-label study as device blinding was not possible which could lead to bias.

## CONCLUSION

Although I-gel is easier to insert with lesser insertion time, Baska mask is more effective in providing greater OLP compared to I-gel without any increase in laryngopharyngeal morbidity explaining its safer use in laparoscopic surgeries with pneumoperitoneum. Further studies needed to evaluate their exact role in the management of high-risk patient with a difficult airway.

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## Conflicts of interest

There are no conflicts of interest.

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